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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,522	09/08/2003	Raymond Bertholet	88265-6925	1947

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EXAMINER

SILVERMAN, ERIC E

ART UNIT PAPER NUMBER

1615

DATE MAILED: 09/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/658,522

Applicant(s)

BERTHOLET ET AL.

Examiner

Eric E. Silverman, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____ | 6) <input checked="" type="checkbox"/> Other: <u>foreign patents and NPL</u> |

DETAILED ACTION

The Examiner assigned to this case has changed. Eric Silverman, PhD, whose contact information can be found at the end of this action, is currently the examiner assigned to this case.

Applicant's response to Non-Final office action, filed May 6, 2005 is acknowledged. Claims 1 – 19 are pending in this action.

Response to Arguments

Applicant's arguments with respect to claims 1 - 19 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7 – 16, and 18 – 19 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: removal of the biomass by centrifugation, removal of insoluble materials by fine filtration, and removal of volatile malodorous materials. Instant claims have the limitation, recited in claim 7 (from which claims 8 – 16 and 18 – 19 depend) of "obtain the stable oil without purification". The specification discloses, however, that it is important to remove the remaining biomass by filtration or centrifugation, to remove insoluble materials by fine filtration, and to remove malodorous content by known methods, of which steam

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distillation and molecular distillation are mentioned. These steps are deemed to be critical to the process for two reasons, namely: 1) they are disclosed in the Specification as being critical steps, and; 2) it would be impossible to use the oil of the claimed invention for its intended use, that is incorporation in a food, pharmacological, or cosmetic composition, without first removing unwanted biological material, insoluble material, and malodorous material since inclusion of such materials would render the product at worst harmful to the human body if the remaining biomass residue or insoluble materials were harmful, and at best unpalatable because of the inclusion of malodorous substances. In either case, the oil would be unfit for the uses disclosed without these steps, and they are thus deemed essential.

Applicant may be his or her own lexicographer, but in this case has not provided a definition of the word "purification". Therefore Examiner has relied upon the definition provided by Webster's New World Dictionary, Third Collage Edition, page 1092, which offers four definitions for the word "purify", the most pertinent to this case being the first and third definitions, which are "to rid of impurities or pollution" and "to free from incorrect or corrupting elements". The word "purification", according to the same source means, "to become purified". Relying upon this definition, the essential steps mentioned above are all deemed to be purification steps, since all of the steps have the effect of ridding the oil of impurities or freeing the oil of corrupting elements, where the impurities or corrupting elements are the remaining biomass, the insoluble materials, or the malodorous compounds.

This being the case, claim 7 as written specifically forbids these steps by reciting the limitation "without purification". Thus claim 7 as written, and thus the claims that depend from claim 7, are expressly limited not to include steps that are deemed essential. Note for example claims 9, 12 and 13 which recite the specific purification steps "pressing and filtration", "molecular distillation or steam distillation" and "final filtration" respectively. These are recitations of specific purification steps, which contradict independent claim 7, which requires "without purification".

Claims 16, and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Instant claims recite "dry or emulsion form". It is not clear what is meant by a "dry form". Does applicant intended only that the product is free of water, or must the form also be free of all liquids in order to be "dry"? Must the product be "dry" only in the sense that no water or liquid is readily apparent, or must it be "dry" in the sense that even miniscule amounts of water, which are not readily apparent to the eye, may not be present? Clarification is requested.

Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Instant claim recites "gentle conditions", "moderate temperature" and "inert atmosphere". It is not clear from the claims, and the specification gives no guidance, what conditions constitute gentle, what temperatures are moderate, and what atmosphere is inert. Clarification is requested.

Regarding claim 12, the phrase "optionally" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Instant claim recites "final filtration". It is not clear what the modifier "final" means. Does this mean that the filtration is the last process step of several consecutive process steps, or does this mean that no other filtrations are to be performed after the one recited in this step? Also, it is not clear how the filtration recited in this step differs from that recited in claim 9. Can this filtration step also be the step recited in claim 9, or must it be a separate step comprising an additional filtration after that of claim 9? Clarification is requested.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by oil used to fry fish.

When fish are fried in oil, the fatty acids in the fish is extracted by and incorporated into the oil used to fry the fish. Fish is known to contain long chain polyunsaturated fatty acids. Some of the oil used to fry the fish adheres to the fish after the fish is cooked, and is eaten along with the fish. This satisfies the limitation that the oil be able to be incorporated directly into a food product without purification. The

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limitations that at least 60% of the long chain fatty acids in the biomass are extracted into the oil and that less than 10% of the phosphorous is extracted into the oil are deemed to be inherent. As Applicant has not specifically defined the term biomass, fish is deemed to be the biomass of instant claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 – 3, 5 – 9, and 14 – 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Todd, US 5,773,075, in combination with Cohen, US 4,235,795 and Barclay, EP 0726321.

Todd teaches a process for the extraction of principle components of plants (wherein the plants constitute a biomass) using an edible solvent (abstract). The process involves pressing and filtration of the unwanted biomass remnants and uses soybean oil (col. 4, line 19 – col. 5, line 63). The solids may be ground if coarse particles are not desired in the residual solid cake (paragraph bridging col. 5 – 6). More than 60% of the extractable material is removed from the biomass (col. 6, lines 43 – 48). No extraction of phosphorous is mentioned, and so such is deemed to be absent.

Todd does not teach extraction of fatty acids using edible oils, nor does Todd teach the extraction of the specific acids mentioned.

Cohen teaches that oil can be used to extract fatty acids from biomasses (foods) that come in repeated contact with the oil (col. 1, lines 6 – 15 and col. 3, lines 24 – 28).

Barclay teaches that PUFA's in general, and arachadonic acid in particular, are important components of a diet, especially in infants (page 2, lines 10 – 21).

Thus, it would have been prime facie obvious to a person of ordinary skill in the art at the time of the invention to use an edible oil to extract PUFAs from a biomass, and specifically to use soybean oil and to extract arachadonic acid. Todd shows in general that extraction of desirable materials from a biomass by using an edible oil is within the skill of the art, and Cohen teaches that edible oils can extract fatty acids in particular. The motivation to combine comes from Barclay, who teaches that particular fatty acids, including arachadonic acid, are desirable dietary supplements. Thus, the artisan, being aware of these teachings, would seek methods known in the art to extract PUFAs from biomasses. Todd teaches such methods, and Cohen suggests that the methods are

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applicable to fatty acids. Because Cohen teaches that fatty acids are extractable by edible oils, the artisan would have a reasonable expectation of success.

Claims 1 – 2, 4 – 9, and 14 – 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Todd, US 5,773,075, in combination with Cohen, US 4,235,795 and Salte et al., US 4,960,795.

The teachings of Todd and Cohen are discussed above.

Salte teaches that docosahexanoic acid is useful as an additive to the feed of atlantic farmed salmon in order to prevent Hitra disease (abstract).

Thus, it would have been prime facie obvious to a person of ordinary skill in the art at the time of the invention to use an edible oil to extract PUFAs from a biomass, and specifically to use soybean oil and to extract arachadonic acid. Todd shows in general that extraction of desirable materials from a biomass by using an edible oil is within the skill of the art, and Cohen teaches that edible oils can extract fatty acids in particular. The motivation to combine comes from Salte, a particular fatty acid, docosahexanoic acid, is a useful additive to the feed of atlantic farmed salmon. Thus, the artisan, being aware of these teachings, would seek methods known in the art to extract PUFAs from biomasses. Todd teaches such methods, and Cohen suggests that the methods are applicable to fatty acids. Because Cohen teaches that fatty acids are extractable by edible oils, the artisan would have a reasonable expectation of success. The expected result would be an soybean oil that is enhanced in PUFAs, and a process of making that oil.

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Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Todd, US 5,773,075, in combination with Cohen, US 4,235,795 and Barclay, EP 0726321 as applied to claims Claims 1 – 3, 5 – 9, and 14 – 19 above, or over Todd, US 5,773,075, in combination with Cohen, US 4,235,795 and Salte et al., US 4,960,795, as applied to claims 1 – 2, 4 – 9, and 14 – 19, above, in either case in further view of Tsujiwaki, US 5,840,945.

The teachings of Todd, Cohen, Barclay, and Salte are discussed above.

These teachings do not suggest the use of an inert atmosphere, or a nitrogen atmosphere, or using tocopherols.

Tsujiwaki teaches that PUFA's are susceptible to oxidation in the air, and that it is routine in the art to add antioxidants such as tocopherols.

Thus, it would be prime facie obvious to a person of ordinary skill in the art at the time of the invention to use a nitrogen atmosphere and to add tocopherols when carrying out the process of instant claims.

The motivation to do so is provided by Tsujiwaki, who teaches that PUFAs are oxidized in the air. The skilled artisan knows that using a nitrogen atmosphere is a method to prevent chemicals from oxidizing in the air, because such oxidation is not possible when oxygen is not present. Tsujiwaki teaches that it is within the skill of the art to add tocopherols to prevent oxidation. The expected result would be a process of making an edible oil that is enhanced in PUFAs wherein the process was carried out under nitrogen atmosphere and where tocopherols were added during the process.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Todd, US 5,773,075, in combination with Cohen, US 4,235,795 and Barclay, EP 0726321 as applied to claims Claims 1 – 3, 5 – 9, and 14 – 19 above, or over Todd, US 5,773,075, in combination with Cohen, US 4,235,795 and Salte et al., US 4,960,795, as applied to claims 1 – 2, 4 – 9, and 14 – 19, above, in either case in further view of Rose et al., EP 0612725 A1.

The teachings of Todd, Cohen, Barclay, and Salte are discussed above.

These teachings do not suggest the use of a final filtration step.

Rose teaches a method of extracting materials from biomasses. Rose teaches the use of a final ultrafiltration step in order to remove unwanted residual material (col. 2, lines 4 – 50, and col. 1, lines 20 – 26).

Thus, it would be prime facie obvious to a person of ordinary skill in the art at the time of the invention to use a final ultrafiltration step in order to remove unwanted residual material. The motivation to do so is to purify the resulting product. Examiner notes that while this step is a purification step, which is prohibited by dependant claim 7 from which instant claim depends, it is nonetheless required by the language of instant claim. This dichotomy has been addressed in this action, under rejections under 35 USC 112. Because such manipulations are within the skill of the art, the artisan would have a reasonable expectation of success. The expected result would be an oil enriched in PUFAs and free of insoluble residual materials.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Todd, US 5,773,075, in combination with Cohen, US 4,235,795 and Barclay, EP 0726321 as

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applied to claims Claims 1 – 3, 5 – 9, and 14 – 19 above, or over Todd, US 5,773,075, in combination with Cohen, US 4,235,795 and Salte et al., US 4,960,795, as applied to claims 1 – 2, 4 – 9, and 14 – 19, above, in either case in further view of Kyle et al., US 5,407,957, of record.

The teachings of Todd, Cohen, Barclay, and Salte are discussed above.

Those teachings do not suggest the use of a distillation step.

Kyle teaches a method of obtaining an oil enriched in PUFA's. Kyle further teaches using distillation to remove hexane, a volatile malodorous compound, in this method (column 6, lines 12 – 13).

Thus, it would be prime facie obvious to a person of ordinary skill in the art at the time of the invention to use a distillation step in order to remove unwanted residual material. The motivation to do so is remove malodorous materials from the product. Examiner notes that while this step is a purification step, which is prohibited by dependant claim 7 from which instant claim depends, it is nonetheless required by the language of instant claim. This dichotomy has been addressed in this action, under rejections under 35 USC 112. Because such manipulations are within the skill of the art, the artisan would have a reasonable expectation of success. The expected result would be an oil enriched in PUFAs and free of volatile malodorous materials.

Conclusion

No claims are allowed. No claims are free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric E. Silverman, PhD whose telephone number is 571

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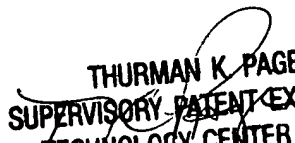
272 5549. The examiner can normally be reached on Monday to Friday 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571 272 0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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